

Remarks

Applicant believes that this amendment places the subject application in better condition for allowance and in so doing introduces no new issues. Therefore, entry of this amendment, reconsideration of the application, and allowance of all claims pending herein is respectfully requested.

Claims 1-43 were originally presented in the subject application. Claims 1, 8, 15 and 23 have been amended. Claims 29-43, drawn to a non-elected invention pursuant to a previous restriction requirement, have been cancelled without prejudice as required in the outstanding Office action. Claims 1-28 remain in this case.

Initially, Applicant wishes to thank Examiner Ramillano for discussing this case with Richard Sampson and Noam Pollack on July 8, 2008. As discussed, Applicant has amended the independent claims to recite test strips having a plurality of test fields/pads with reagents disposed thereon. Claims 1 and 8 have also been amended to recite marker fields on the test strips, and the step of identifying the strip using the marker fields as recited in original claim 15. Support for the plurality of test pads/fields with reagents may be found in original claim 8, which recited a test strip having “specified reagents” disposed at “reagent positions” on the strip. Additional support for this amendment may be found in the application as filed, which recites “[a]fter the color coding sequence has been identified, the instrument... will move the test strip to the test fields.” (Published application, par. [0028]). Support for the remaining amendments of marker fields and the identification step may be found in original claim 15. As such, Applicant respectfully submits that no new search is required and no new matter has been added.

Rejections under 35 U.S.C. §102(b)

Howard, III (U.S. Patent No. 5,945,341)

Independent claims 1, 8 and 15 (and claims depending therefrom), stand rejected under §102(b) as anticipated by Howard, III, U.S. Patent No. 5,945,341 (Howard '341). To the extent deemed pertinent in light of the amended claims, Applicant respectfully traverses this rejection.

As discussed above, claims 1, 8 and 15 now each recite a test strip having a plurality of test pads/fields, and a separate and distinct set of marker fields. Howard '341 discloses only a single test field 501, and for at least this reason, should be viewed as failing to anticipate Applicant's claimed invention.

These claims also each recite an identification step in which the marker fields are used to identify the strip, and a separate misidentification step in which IR reflectances from the test pads/fields are checked to effectively double-check the aforementioned identification step.

The Office action has characterized Howard '341 as disclosing this misidentification step, citing col. 8, line 49 to col. 9, line 8 of Howard '341. (Office action, p. 4).

This cited portion of Howard '341 refers to a "test control region 502", the analysis of which "will indicate whether or not the proper procedural methods were followed." (Howard '341, col. 8, lines 55-57). Howard further explains that this "control region 502... will generate a specific color if the proper procedures for the test [are] followed by the user. More particularly, if the test strip were not exposed to sufficient sample, this procedural fault will be detected." (Howard '341, col. 9, lines 10-13.)

Applicant respectfully submits that this "control region 502" is not a test pad/field as now claimed. Rather, as described, it is simply a control region which is separate and distinct from an actual test pad/field. Indeed, Howard's test region is shown and described as a separate "test region 501". Thus, for this alternative reason, Applicant respectfully submits that Howard's disclosed use of test control region 502 does not anticipate the invention as now claimed.

Moreover, this cited portion of Howard '341 discloses that "test region 501... is measured in the infrared (IR), red, green, and blue spectral regions" and "the ratio of the reflectance in the green to the reflectance in the infrared may be computed and then compared with a table of ratio ranges to decode the concentration of the substance that will be reported to the user. If there was no error, the analysis results may be reported on printer 32 FIG. 1." (Howard '341, col. 8, line 63 to col. 9, line 8).

This recitation does not disclose that the IR reflectance itself is checked to determine whether it is within an acceptable range as claimed by Applicant. Rather, Howard simply looks at a ratio of a plurality of reflectances (i.e., of IR to non-IR reflectances). Analysis of a ratio is

not the same as analysis of an individual reflectance. Moreover, there is nothing in Howard '341 to teach or suggest that the recited "error" in decoding the concentration of the particular analyte, corresponds to misidentification. Rather, when this particular passage is read in the context of the rest of the paragraph of which it is a part, it is apparent that this particular decoding "error" refers to errors generated by improper procedural methods, such as insufficient exposure to sample, as discussed above. In addition, rather than correlating this error to Applicant's claimed misidentification, Howard discloses only that such an error may be used to avoid displaying erroneous results on the printer. (Howard '341, col. 9, lines 7-8).

The Office action further indicates that error testing of reflectances from the test field (501) "inherently refers to a misidentification of the test strip" because elsewhere (in col. 1, lines 6-8), Howard teaches that separate marker fields 504 may be used for "optical identification of test strips". (Office action, p.11). Applicant respectfully submits, however, that this disclosure by Howard corresponds to the initial "identification" step of claims 1, 8 and 15, and not to the subsequent claim step of determining "misidentification" of the test strip. Indeed, as recited in the claims, and as discussed in the specification, the "identification" and "determining... misidentification" are two separate and distinct steps, with the latter solving the stated problem of catching inaccuracies in the former. As such, Howard's disclosure of the "identification" step cannot also be deemed to inherently disclose Applicant's separate and distinct "misidentification" step.

In light of the foregoing, Applicant respectfully submits that Howard '341 fails to anticipate the amended independent claims. Howard '341 does not disclose determining whether the strip has been misidentified, based on the infrared reflectances of the reagent test pads/fields, as claimed. While Howard '341 discloses identifying the strip based on a coded sequence of marker fields, it fails to disclose the follow-on verification step of determining the misidentification of the strip based on IR reflectances from reagents on test pads/fields.

Rejections under 35 U.S.C. §102(c)

Corey et al., U.S. Patent No. 6,316,264

Independent claims 1 and 8 (and dependent claims 2-3, 5, 7, 9, 10, 12, and 14) stand

rejected under § 102(c) as anticipated by Corey et al., U.S. Patent No. 6,316,264. To the extent deemed relevant in light of the amended claims, Applicant respectfully traverses this rejection.

The Office action indicates that Corey teaches the step of determining whether a test strip is misidentified in, for example, column 14, lines 8-20. In this cited portion, Corey describes his Example 3, in which colored tapes placed on a test strip were determined to generate false positive or false negative test assays. Based on these test results, Corey determined “that a visibly colorless dye, i.e., an IR dye, must be used as the marker to ensure proper alignment of a test strip in spectrophotometer.”

Applicant respectfully submits that Corey fails to disclose Applicant’s claim step of identifying the test strip by reading reflectances of one or more of the plurality of marker fields, which marker fields are distinct from a plurality of test pads/fields. Thus, Applicant respectfully submits that for this reason alone, Corey fails to anticipate the claimed invention.

In addition, there is nothing to indicate that Corey’s false positive/negative results equate to Applicant’s claimed “misidentification” of a test strip. In other words, a simple erroneous result does not necessarily equate to misidentification, since there could be any number of reasons for false positive/negative results. In this cited Example, the erroneous results simply indicate that the strip reader may be confused by deliberately adding visibly colored tapes to the test fields.

For either of the foregoing reasons, Applicant therefore respectfully submits that Corey fails to anticipate the claimed invention.

Rejections under 35 U.S.C. §103(a):

Howard, III (U.S. Patent No. 5,945,341) and Howard, III, et al. (U.S. Patent No. 5,654,803)

Independent claim 15 (and dependent claims 16-17, 23-25 and 28) stands rejected under 103(a) as unpatentable over Howard ‘341 and Howard, III, et al. (U.S. Patent No. 5,654,803, “Howard ‘803”). To the extent deemed relevant in light of the amended claims, Applicant respectfully traverses this rejection.

The Office action indicates that Howard ‘803 discloses most of the characteristics of Applicant’s claim 15, but “Howard ‘803 does not specifically teach the step of determining if a

test strip is misidentified”. As discussed above, the Office action maintains that this misidentification step is disclosed by Howard ‘341, and further states that it “would have been obvious... to modify Howard ‘803 in view of Howard ‘341 because it would be desirable to have a method of determining whether a test strip is misidentified to insure that test results produced from a test strip are accurate.” (Office action, p. 10).

However, for the reasons discussed above, Applicant respectfully submits that Howard ‘341 does not in fact disclose the claimed misidentification step.

It is well settled that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP § 2143.03. As discussed above, Howard ‘341 does not disclose or suggest determining whether a test strip has been misidentified, based on whether the infrared reflectance of reagents on a test pad/field are within an acceptable predetermined range. Instead, as discussed above, Howard ‘341 discloses identifying the strip based on a coded sequence of marker fields, but neither discloses nor suggests the additional verification step of determining whether the strip had actually been misidentified, by analyzing the IR reflectance of separate test pads/fields. In this regard, as also discussed above, the error associated with the ratio of reflectances from Howard ‘341’s test region 501 is used solely to avoid displaying erroneous results, such as due to improper testing procedures. Neither Howard ‘341, nor any of the other cited references, teach or suggest the need for a secondary “misidentification” step to verify prior strip identification.

Therefore, for at least any one of the foregoing alternative reasons, Howard ‘341 does not render Applicant’s claimed invention obvious. Applicant therefore respectfully requests withdrawal of this ground of rejection.

CONCLUSION

For at least the foregoing alternate reasons, Applicant respectfully requests reconsideration and allowance of the pending claims. The dependent claims are believed to be allowable for the same reasons as the independent claims from which they depend, as well as for their own additional limitations. Applicant therefore further submits that all of the stated

grounds of objection and rejection have been properly traversed, accommodated, or rendered moot.

This application is now believed to be in condition for allowance, and such action at an early date is respectfully requested. However, if any matters remain unresolved, the Examiner is encouraged to contact the undersigned by telephone.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-0734** referencing Docket No. MSE #2620. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'R. L. Sampson', followed by a horizontal line.

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